EC - DECLARATION OF CONFORMITY

In compliance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

MOUTHIES Earloop face masks, latex - free

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REF	PRODUCT DESCRIPTION		C = MP Class R = Rule	UMDNS
8506DB-RS	1x50	The disposable, earloop face masks are intended to protect both the wearer and the patient from contamination caused by microorganisms through the drops and blood splashes, saliva, or wastewater, and when dealing with contaminated instruments.	CI - R1	12458
8506DB-R	40x50			

Harmonised standards and normative documents:

EN 14683:2014, TYPE IIR (BFE ≥ 98%, splash resistant)

We hereby declare that the above mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations by bearing CE-marking.

Version: 3

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Department: Regulatory Affairs

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